DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-007/S-031
NDA 20-007/S-032
NDA 20-403/S-010
NDA 20-403/S-011

Glaxo Wellcome Inc.
Attention: Roger R. Gaby
Product Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Gaby:

Please refer to the following supplemental new drug applications, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act:

- NDAs 20-007/S-031 and 20-403/S-010, submitted December 22, 1999, received December 23, 1999 for Zofran (ondansetron) Injection and Premixed, respectively; and

- NDAs 20-007/S-032 and 20-403/S-011, submitted May 22, 2000, received May 23, 2000 for Zofran (ondansetron) Injection and Premixed, respectively.

We acknowledge receipt of your submission dated October 4, 2000 to NDAs 20-007/S-031 and 20-403/S-010. Your submission of October 4, 2000 constituted a complete response to our August 4, 2000 action letter.

These supplemental new drug applications provide for the following:

NDAs 20-007/S-031 and 20-403/S-010 provide for the addition of a Geriatric Use subsection in the PRECAUTIONS section of the package insert and modification to the CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION sections of the package insert in accordance with 21 CFR 201.57(f)(10)(iii)(A); and

NDAs 20-007/S-032 and 20-403/S-011 provide for revision of the package insert to include "ST segment depression" in the ADVERSE REACTIONS section, Observed During Clinical Practice subsection.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental

applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 4, 2000).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-007/S-031, 20-007/S-032, 20-403/S-010, 20-403/S-011." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Melodi McNeil, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research